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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,096	01/24/2005	Thomas Ehrhardt	BASF. 10027	9245

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EXAMINER	
SAIDHA, TEKCHAND	
ART UNIT	PAPER NUMBER
1652	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,096	EHRHARDT ET AL.	
	Examiner	Art Unit	
	Tekchand Saidha	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-7,9-15,18-20 and 22-25* is/are pending in the application.

4a) Of the above claim(s) *2-7,14,18,19 and 22-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-13,15,17 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/24/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 2-7, 9-15, 18-20, 22-25 are present in this application

2. ***Election/Restriction***

Applicant's election with traverse of Group IV, claims 9-13, 15, 17 & 20 (SEQ ID NO: 1) in reply filed 3/21/07 is acknowledged. The traversal is on the ground(s) that there is a **unity of invention** with respect to Groups I-VIII.

Applicants respectfully traverse the restriction requirement and the single sequence requirement and provisionally elect the subject matter of group IV, presented in claims 9-13, 15, 17, and 20, drawn to a method of identifying herbicidally active substances using the polypeptide of SEQ LD NO: 2 or 4 or 6 (or the encoding nucleic acid sequence of SEQ lid NO: 1 or 3 or 5) and compound identified, and further elect the single nucleic acid sequence of SEQ ID NO: 1 for further prosecution.

The restriction is traversed for the following reasons. 37 C.F.R. § 1.475(a) states that unity of invention is full filled if "there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" is defined as those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The claims of the present application include the use of sucrose-6-phosphate phosphatase as an herbicidal target and methods using same to identify herbicidal active substances. Inhibition assays are disclosed for use in identifying herbicidal compounds among the method claims of Group IV. The methods

disclosed can be based on growth-regulatory activity assays, as in the claims of Group V and use the agrochemical composition prepared in the claim of Group VI. In addition, the methods disclosed can employ the use of nucleic acid sequences encoding polypeptides having the biological activity of sucrose-6-phosphate phosphatase generated by the methods of Group VII, and transgenic plants generated by the methods of Group VIII. In using the methods disclosed, various nucleic acid sequences, functional analogs, or polypeptide sequences can be used, *inter alia*, Groups I through III. Thus, Groups I through VIII all share a technical relationship when the claimed invention is considered as a whole. Reconsideration and withdrawal of the Restriction requirement is respectfully requested.

The argument is considered and found not persuasive because Applicants arguments do not identify or address the "special technical features" of their invention. Further, Applicants fail to address the art cited by the Examiner as per "The international preliminary examination report [IPER] submitted by the Applicants, wherein the teachings of Lunn et al. ['Purification, molecular cloning, and sequence analysis of sucrose-6F-phosphate phosphatase from plants', PNAS, Vol. 97, No. 23, (7 November 2000), pages 12914-9], anticipate claims 2 & 3, for example, for lacking novelty. Thus not a contribution over prior art. The lack of unity determination is still deemed proper and is therefore made FINAL.

3. Further, Applicants arguments are considered but not found to be persuasive because each of the nucleic acid sequences as identified by the SEQ ID NO: X are structurally as well as in the level of the encoding enzyme activity are distinct from each other.

Official Announcement Regarding Restriction Practice in Applications Containing Nucleotide Sequences (March 12, 2007).

By Christopher P. Singer ---

The USPTO published a pre-OG notice regarding its new position on restriction practice in pending applications that relate to nucleic acid sequences. Prior to this notice, the PTO had been officially operating under the direction of an Official Gazette notice dated November 19, 1996. The old notice allowed for a partial waiver of requirements for restriction and unity of invention for applications relating to nucleotide sequences by permitting examination of a "reasonable" number -- typically up to ten -- independent and distinct molecules described by their nucleotide sequences in a single patent application. This newly published notice effectively rescinds the 1996 notice, and requires that claims to polynucleotide sequences "be considered for independence, relatedness, distinction and burden as for claims to any other type of molecule." Effectively, this means that applicants will be allowed to claim only a single polynucleotide sequence per patent application.

The notice lists a number of factors that motivated the change, the most interesting of which (to me) is the 54-fold increase in the number of nucleic acid sequences in the GenBank® database (and a 91-fold increase in the number of nucleotides) between 1996 and February 2006. Further, the Office believes that this change will provide applicants with a more focused and consistent course of examination, as a result of the decrease in the search and examination burdens.

This notice provides an official change in the PTO's policy regarding the treatment of inventions relating to polynucleotide

sequences. However, this change likely will have little to no effect on the day-to-day practice of biotech restriction practice, as this notice seems to postdate what has already become common practice at the PTO. The requirement is still deemed proper and is therefore made FINAL.

3. Claims withdrawn:

Claims 2-7, 14, 18-19 & 22-25 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. ***Priority***

Acknowledgment is made of applicants' claim for priority based on an application filed in Germany on July 23, 2002.

5. ***Specification***

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

6. Claims 9-13, 15, 17 & 20 and SEQ ID NO: 1 are under consideration in this Office Action.

7. ***Claim Objections***

Claims 9-13, 15, 17 & 20 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims depend upon non-elected claims, and further recite non-elected subject matter. Amending the claim(s) to place the claim(s) in proper depended form and deleting non-elected subject matter from the claims is required.

8. ***Enablement Rejection***

Claims 9-13, 15, 17 & 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying herbicidally active substances using a polypeptide having sucrose-6-phosphate phosphatase activity encoded by DNA (or polynucleotide) molecules of SEQ ID NO: 1, does not reasonably provide enablement for a method of identifying herbicidally active substances using variant polypeptides encoded by DNA (or polynucleotide) molecules wherein DNA sequence is 55% identical to SEQ ID NO: 1 or functional equivalent thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The scope of the claims does not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide sequence(s) of SEQ ID NO: 1 or 3 [*Nicotiana tobacum*] or SEQ ID NO: 5 [*Solanum tuberosum*] and the encoded amino acid sequence of SEQ ID NO: 2 or 4 or 6.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications of DNA of SEQ ID NO: 1 or a DNA by 45%, because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting sucrose-6-phosphate phosphatase activity; (B) the general tolerance of sucrose-6-phosphate phosphatase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any sucrose-6-phosphate phosphatase residues with an expectation of obtaining the desired enzymatic or functional equivalent capable of catalyzing a defined chemical reaction using known substrates; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

This is further supported in the work of Seffernick et al. [J. Bacteriol. Apr. 2001, p. 2405-2410] where melamine Deaminase and Atrazine chlorohydrolase each consists of 475 amino acids, are 98% identical and are yet functionally different. Thus there is high unpredictability associated with respect to

modification(s) of the sequence of SEQ ID NO: 1 unless guidance is provided in establishing (A) - (D) as discussed above.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of exact nature of the encoding DNA (or polynucleotide) encoding a specific sucrose-6-phosphate phosphatase of known substrate specificity having the desired enzymatic characteristics to be used in the instant method is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

9. ***Claim Rejections - 35 USC § 112*** (second paragraph)

Claims 9-13, 15, 17 & 20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9-13, 15, 17 & 20 in an independent or dependent manner recite the phrase 'functional equivalent' which is vague and indefinite. The phrase is vague and indefinite because it is unclear what other functional equivalency is meant or associated with, other than the specific sucrose-6-phosphate phosphatase activity that is defined in the specification. Deletion of the phrase is suggested to overcome this rejection.

10. ***Written Description***

Claims 17 & 20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described

in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of herbicidally active compound identified via one of the methods of claims 9, 10 or 11 (claim 17), or a genus of method for controlling undesired vegetation and/or for regulating growth of plants using at least one compound of claim 17 to act on plants, their environment and/or on seeds.

The specification does not contain any disclosure or description of the structure and function of even a single compound so identified, nor a method of using the compound so identified. It is also not known how these unidentified compound(s) be used can therefore be used in controlling undesired vegetation or in regulating plant growth. The genus of compound(s) or method(s) that comprise these herbicidally active molecules is a large variable genus with no clear basis in even a single exemplified species.

The specification discloses no herbicidally active compound or method using the compound (or species) of the claimed genus which is insufficient or rather impossible to put one of skill in the art in possession of the attributes and features of all species within the claimed genus.

In order that the method be described, all the elements or the product(s) required to carry out the method must be also described. In the instant case the 'herbicidally active compound' used in the method is key for the method to be functional and is not described in the specification to the extent required in order to meet the written description

requirement as explained above. This is supported by the decision of the following CAFC case, which is briefly described.

See University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 CAFC 2004), wherein, "A method patent for treating the side effects of pain relievers is invalid for failing to adequately describe the compound used in the claimed method, the U.S. District Court for the Western District of New York rules. Granting a summary judgment motion, the court reasons that the written description requirement of 35 U.S.C. §112 ¶1 cannot be satisfied by merely providing the desired function of the compound without more detail on the compound's structure, chemical formula, chemical name, or physical properties. The court also stresses the applicability of the written description requirements to the compound used, even though the patent consists of method claims rather than compound claims. In the instant case neither the compound nor the method claims remain described.

Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

11. No claim is allowed.

12. According to the international preliminary examination report [IPER] submitted by the Applicants, Lunn et al. ['Purification, molecular cloning, and sequence analysis of sucrose-6F-phosphate phosphatase from plants', PNAS, Vol. 97, No. 23, (7 November 2000), pages 12914-9, PTO-1449], teach cloning of sucrose-6F-phosphate phosphatases from various plants (page 12915, figure 2, table 3) and their expression in *Escherichia coli*. The disclosed sequence AF283565 of *Arabidopsis thaliana* is approximately 70% identical to the claimed nucleotide sequences

and 80% identical to the amino acid sequences and therefore anticipate **non-elected** claims 2 & 3, for example. However, the reference does not teach or provide motivation to make the instantly claimed method claims obvious.

13. Status of the claims:
(1) Claims 2-7, 9-15, 18-20, 22-25 are present.
(2) Claims 9-13, 15, 17 & 20 (SEQ ID NO: 1) are rejected.
(3) Claims 2-7, 14, 18-19 & 22-25 are withdrawn.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272 0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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